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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,186	12/28/2001	Harish Mahalingam	680.0054USU	7732

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EXAMINER
PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
1654	12

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/034,186	MAHALINGAM ET AL.	
	Examin r	Art Unit	
	Patricia A Patten	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/23/03* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *4,5 and 15-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-3 and 7-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-30 are pending in the application. Claims 14-30 were withdrawn (without traverse) from further consideration on the merits in Paper No. 8.

Election/Restrictions

Applicant's election of the specie of 'coconut water' in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Because claims 4 and 5 are not drawn to the elected specie, these claims have been withdrawn from consideration on the merits.

Claims 1-3 and 6-13 were examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an aqueous perilla extract, does not reasonably provide enablement for any perilla extract. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

In the Instant case, Applicants have claimed a composition comprising coconut water in combination with a melanin uptake-inhibiting agent, wherein said agent is any extract of perilla; i.e., seed, leaf, stem or fruit. However, Applicants have not disclosed any perilla extract, besides the aqueous extract which would actually perform this function. For example, what other extract will perform this function? Is this extract a benzene extract, an alcoholic extract, a hydroalcoholic extract or a supercritical extract for example? It is deemed that this lack of critical information would preclude the skilled artisan from making or using the claimed invention within the large breadth of the claimed scope.

It is well known in the herbal art that polarity of solvents plays a key role in determining the final product obtained by an extraction. However, because many phytochemicals remain undiscovered, the skilled artisan has to make his best educated guess as to what types of phytochemicals will be successfully extracted with a solvent of a particular polarity. Often times, unless the constituents in a particular plant extract have been well evaluated and documented in the literature, the skilled artisan must adhere to trial and error protocols in order to quantitatively determine phytochemical constituents present in samples obtained from respective extraction procedures. These procedures are common when, for example, a plant or part thereof has been documented in the literature as possessing some medicinal quality. The skilled artisan will carry out numerous tedious extraction protocols in attempt to isolate the particular

ingredient(s) which has/have this medicinal quality. Typically, beginning with the first crude extraction, ***it is a guess*** as to weather or not the extract will possess the inherent medicinal quality. Take for example, the grape, *Vitis vinefera*. If this fruit was documented in the literature as having a particular medicinal qualities, the skilled artisan may feel the need to extract and isolate the medicinally beneficial ingredient(s)therefrom.

The skilled artisan will, by trial and error, attempt to perform step-wise extractions to uncover the active extract. If the first extraction attempt with a particular solvent fails, another solvent will be tried. Thus, beginning with the initial extraction, a first product is yielded which was extracted with the solvent, and a second product is yielded which remains because it did not possess a similar polarity to the solvent. Each successive extraction yields different products due to the exclusion of ingredients based on the polarity of the solvents solvating constituents with similar polarities. Subsequently, *the properties of each respective product (extract) would need to be evaluated for efficacy*.

Additionally, according to the Stedman's dictionary 27th Ed, the term 'extract' means 'A concentrated preparation of a drug obtained by removing the active constituents of the drug with suitable solvents...'. Thus, purification of any product obtained via an extraction to yield a specific phytochemical would constitute an 'extract' judging from the definition provided by Stedman's Medical Dictionary. Therefore,

resveratrol, a phytochemical inherent in grapes, is deemed to be an 'extract' of grapes since it is obtained by the process outlined in Stedman's. Therefore, each respective phytochemical found within grapes constitutes an extract once it is 'extracted' away from the rest of the grape's constituents. Here, the unpredictability with regard to the term 'extract' in the claims has grown exponentially.

Hence, each product obtained from a plant extraction is unpredictable in nature. Even the most skilled of artisans would need to quantify each product for constituents as well as medicinal efficacy. Unpredictability with regard to plant extracts has been well documented in the art. Revilla et al. for example (1998) showed that the slightest variations in polarity of solvent and reaction time upon grape extraction, provided respective products with unique characteristic properties (See Tables 1, 2, 4, 5, 6 and 7). In turn, each product would possess varying pharmacological properties based upon their respective phytochemical constituents.

Applicants have not provided any information with regard to how to make any 'extract' of perilla besides an aqueous extract (Fig. 1) . Thus, to practice the instant invention in a manner *consistent with the breadth of the claims* would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner to ascertain what other perilla extract actually performed the intended function as recited in the claims (melanin uptake-

inhibiting function). This inventive contribution would involve tedious trial and error protocols without the expectation of success for the reasons set forth *supra*.

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

This rejection may be overcome by amending the claims to recite 'aqueous extract of perilla'.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

Claims 1-3 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by International Product Alert (1994).

Claims 1-3 are drawn to a composition comprising a topical lightening agent and a vehicle, wherein the topical lightening agent is coconut water. Claims further state that the lightening agent is in an amount effective to inhibit DOPAchrome tautomerase, DHICA polymerase or both, wherein the topical lightening agent has a melanin synthesis-regulating agent and wherein the composition is in a form such as a 'pump spray'.

International Product Alert (IPA) (1994) disclosed a beverage comprising coconut water diluted with natural water (please see one page full text document).

Although IPA did not specifically teach that the product was a lightening agent, it is noted that the term 'lightening agent' is merely an intended use for the coconut water,

and does not hold much patentable weight because it does not materially change the physical characteristics of the coconut water.

Further, although IPA did not disclose the amount of coconut water in the beverage, or that the coconut water inhibited DOPAchrome tautomerase or DHICA Polymerase, it is deemed that these mechanisms would have taken place as a result of inherent consequence. The Instant specification teaches that 0.02% of coconut water wt/vol inhibited 50% of DOPAchrome conversion and 0.05% wt/vol inhibited 75% of DOPAchrome conversion. Therefore, it is deemed that the coconut water, possessing this inhibiting activity, would have inherently provided this activity at any amount, especially lacking sufficient evidence to the contrary.

The term 'pump spray' has been interpreted to mean that the composition is in the form of a liquid which can be sprayed out of a pump. Because IPA disclosed that the composition was in liquid form, it is deemed that the composition was a liquid, and could have been sprayed out of a pump thereby anticipating claim 13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over IPA (1994). The nature of claims 1-3 and 13 was discussed in the previous rejection under 35 USC 102 (b). Claims 10-12 are drawn to wherein the lightening agent is present at different weight ratios in the total weight of the composition.

The teachings of IPA were discussed *supra*.

IPA did not specifically discuss the amount of coconut water present in the beverage manufactured by Kachiwari.

One of ordinary skill in the art would have been motivated to have varied the amount of coconut water in the beverage in order to manufacture drinks with fluctuating enhanced flavor; i.e., 'regular' and 'extra' coconut flavor. Variations in flavoring constituents within nutritional compositions was routine in the food/nutritional art; to do so was considered routine optimization of flavoring additives.

It is noted that a rejection under 35 U.S.C. § 103 based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention. Ex parte Raychem Corp, 17 U.S.P.Q. 2d 1417. Here, although

Applicants may have combined the Instant ingredients for a particular intended use; i.e., skin lightening, it does not preclude the obviousness of the claimed rejection for the reasoning outlined *supra*.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 6-9 are free of the art and will be allowed if amended to overcome the rejection under 35 USC 112 first paragraph *supra*.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

August 08, 2003

Patricia Patten